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K960281

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:

K960281

(To be completed by FDA)

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A. GENERAL INFORMATION

Device Classification Name:

Electrode, Pacemaker, Permanent and Temporary

Device Trade Name:

Implantable Pacing Leads

- Intermedics Model 431-04 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Model 431-07 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Model 433-02 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Model 433-03 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix Model 435-02 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix EZ Model 435-05 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix EZ Model 435-07 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Cardifix XRI Model 435-08 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Model 437-02 Bipolar Implantable Endocardial Pacing Lead
- Intermedics Model 437-07 Unipolar Implantable Endocardial Pacing Lead
- Intermedics Model 439-04 Unipolar Polyflex Epicardial Implantable Pacing Lead
- Intermedics Lifeline Myocardial Sutureless Model 439-07 Unipolar Implantable Pacing Lead

Implantable Accessories

- Intermedics Model 365-07 5mm Lead Connector Cap
- Intermedics Model 365-09 5mm to 6mm Adapter Sleeve
- Intermedics Model 365-14 6mm Helical Coil Adapter
- Intermedics Model 365-17 Elema Adapter Kit
- Intermedics Model 365-19 Splicing Crimp and Splicing Sleeve
- Intermedics Model 365-22 Lead Suture Sleeve
- Intermedics Model 365-33 Insulating Sleeve
- Intermedics Model 365-34 5mm Helical Coil Adapter
- Intermedics Model 365-44 Lead Suture Sleeve

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- Intermedics Model 365-49 Implantable 5mm Connector Receptacle Plug
- Intermedics Model 366-13 6mm to VS.1 In-Line Bipolar Step-down Adapter
- Intermedics Model 366-15 VS.1 Pacer Plug
- Intermedics Model 366-27 5mm to VS.1 Step-down Adapter
- Intermedics Model 366-28 6mm to VS.1 Step-down Adapter
- Intermedics Model 366-29 VS.1 to 5mm Step-up Adapter
- Intermedics Model 366-30 VS.1 to 6mm Step-up Adapter

Non-implantable Accessories

- Intermedics Model 365-62 Vein Markers/Lead Tags
- Intermedics Model 365-77 Retraction Stylet
- Intermedics Model 365-29 6 Foot Extension Cable for External Pacemaker
- Intermedics Model 366-02 Temporary Wire Extension for Adapting a Permanent Pacing Lead to an External Pacemaker
- Intermedics Model 366-17 PSC VS.1 Pacer Test Cable
- Intermedics Model 367-01 Vein Lifter

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Date of Notification:

January 18, 1996

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B. DESCRIPTION OF THE DISEASES AND CONDITIONS FOR WHICH THE CFC-FREE MANUFACTURED PACING LEADS ARE INDICATED

The indications for use of Intermedics Models 431-04, 431-07, 433-02, 433-03, 435-02, 435-05, 435-07, 435-08, 437-02, and 437-07 endocardial pacing leads, model 439-04 epicardial pacing lead, model 439-07 myocardial pacing lead, implantable accessory models 365-07, 365-09, 365-14, 365-17, 365-19, 365-22, 365-33, 365-34, 365-44, 365-49, 366-13, 366-15, 366-27, 366-28, 366-29, and 366-30, and non-implantable accessory models 365-62, 365-77, 365-29, 366-02, 366-17, and 367-01, manufactured using a Chlorofluorocarbon (CFC) Free process, are identical to those for the commercially available leads and accessories with the same model numbers manufactured using Freon-TMS.

Pacing leads and accessories are intended for use with implantable cardiac pulse generators for long-term pacing of the heart. The indications for ventricular pacing include, but are not limited to: Sick sinus syndrome, sinus bradycardia, complete heart block, and certain conditions of asymptomatic second-degree block.

In the presence of normal A-V conduction the indications for atrial pacing include, but are not limited to: Sinus arrest, sick sinus syndrome, sinus bradycardia and conditions requiring increased cardiac efficiency, enhanced cardiac output or the overdrive of certain cardiac arrhythmias.

In the absence of normal A-V conduction, an atrial lead may be used with a ventricular lead in a dual-chamber pacing system to restore A-V synchrony.

Active fixation leads are specifically indicated for use in cases where passive-fixation leads provide unsatisfactory positional stability in either the atrium or the ventricle, or in cases where the atrial appendage has been sacrificed due to open-heart surgery or is abnormal because of congenital or acquired heart disease.

Suture-on epicardial leads (model 439-04) and screw-on (sutureless) myocardial leads (model 439-07), placed on the outside of the heart, are indicated for use when cardiac pacing is indicated and a suture-on lead is preferred, or when an endocardial lead cannot achieve satisfactory results. Such leads are particularly well suited to patients whose age or heart condition requires that the potential

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for lead dislodgment be minimized (i.e. patients who have not reached full physical maturity) and patients who may require cardiac pacing following open-chest surgery.

Contraindications

The use of endocardial leads may be contraindicated in the presence of tricuspid atresia, Ebstein's malformation, and various forms of atrial or ventricular transposition, and in patients with mechanical tricuspid heart valves. The use of endocardial leads for atrial indications may be contraindicated in the presence of atrial paralysis, atrial atrophy, or a surgically modified or excised atrial appendage.

Atrial pacing is contraindicated in the presence of atrial fibrillation and, except when used in a dual chamber system, in the presence of certain A-V conduction defects.

Suture-on epicardial leads (model 439-04) and screw-on (sutureless) myocardial leads (model 439-07) are contraindicated for use when the electrode is placed over infarcted myocardium. Sutureless myocardial leads are contraindicated for use in patients with serious underlying cardiac disease such as congestive heart failure and advanced coronary artery disease, in elderly debilitated patients and in patients with pulmonary disease and/or renal dysfunction.

C. DEVICE DESCRIPTION

The Intermedics Models 431-04, 431-07, 433-02, 433-03, 435-02, 435-05, 435-07, 435-08, 437-02, and 437-07 endocardial pacing leads, model 439-04 epicardial pacing lead, model 439-07 myocardial pacing lead, implantable accessory models 365-07, 365-09, 365-14, 365-17, 365-19, 365-22, 365-33, 365-34, 365-44, 365-49, 366-13, 366-15, 366-27, 366-28, 366-29, and 366-30, and non-implantable accessory models 365-62, 365-77, 365-29, 366-02, 366-17, and 367-01, are designed for use with implantable cardiac generators for long term cardiac pacing. Table 1 summarizes the accessories packaged with each lead model.

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TABLE 1. Accessories packaged with each lead model.

Accessory	Lead Model					
	431-04	431-07	433-02	433-03	435-02	435-05
365-11 Limber Stylet	✓	✓	✓	✓	✓	✓
365-12 Firm Stylet	✓	✓	✓	✓	✓	✓
365-57 Limber Large "J" Stylet					✓	✓
365-58 Firm Large "J" Stylet					✓	✓
365-81 Tapered Limber Stylet						
365-82 Tapered Firm Stylet						
365-87 Limber Tight "J" Stylet					✓	✓
365-89 Limber "J" Stylet						
365-90 Firm "J" Stylet						
366-14 Lead Cover						
366-29 Step up adapter VS.1 to 5mm	✓	✓	✓	✓	✓	✓
366-30 Step up adapter VS.1 to 6mm	✓	✓	✓	✓	✓	✓
367-01 Vein Lifter	✓	✓	✓	✓	✓	✓
Stylet Funnel (no model no.)	✓	✓	✓	✓		

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TABLE 1 (CONT.). Accessories packaged with each lead model.

Accessory	Lead Model					
	435-07	435-08	437-02	437-07	439-04	439-07
365-11 Limber Stylet	✓	✓	✓	✓		
365-12 Firm Stylet	✓	✓	✓	✓		
365-57 Limber Large "J" Stylet		✓				
365-58 Firm Large "J" Stylet		✓				
365-81 Tapered Limber Stylet				✓		
365-82 Tapered Firm Stylet				✓		
365-87 Limber Tight "J" Stylet		✓				
365-89 Limber "J" Stylet	✓					
365-90 Firm "J" Stylet	✓					
366-14 Lead Cover					✓	✓
366-29 Step up adapter VS.1 to 5mm	✓	✓	✓	✓	✓	✓
366-30 Step up adapter VS.1 to 6mm	✓	✓	✓	✓	✓	✓
367-01 Vein Lifter	✓	✓	✓	✓		
Stylet Funnel (no model no.)		✓				

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With the exception of the solution used during the manufacturing process, the listed pacing leads and accessories manufactured with the CFC-free process are identically configured to the commercially available Intermedics pacing leads and accessories with the same model numbers. Table 2 lists the 510(k) numbers and approval dates for each lead model.

Table 2. 510(k) Numbers and approval dates for each lead model.

Lead Model	510(k) Number	Approval Date
431-04	K883602	09/06/88
431-07	K890412	03/28/89
	K902672	03/01/91
	K954610	Submitted 10/03/95
	K954719	Submitted 10/12/95
433-02	K883602	09/06/88
433-03	K890411	03/28/89
	K912235	09/26/91
	K954610	Submitted 10/03/95
	K954719	Submitted 10/12/95
435-02	K862276	07/02/86
	K954719	Submitted 10/12/95
435-05	K922972	01/22/93
	K954719	Submitted 10/12/95
435-07	K955550	Submitted 12/04/95
435-08	K922042	04/29/93
437-02	K883602	09/06/88
	K954719	Submitted 10/12/95

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Table 2. 510(k) Numbers and approval dates for each lead model.

Lead Model	510(k) Number	Approval Date
437-07	K955122	Submitted 11/07/95
439-04	K874531	01/07/88
	K954719	Submitted 10/12/95
439-07	K880551	03/07/88
	K954719	Submitted 10/12/95

1. **Labeling**

There are no changes to the product labeling as a result of the modification to the manufacturing process.

2. **Design and Materials**

The general characteristics of the pacing leads are summarized below. Table 3 summarizes the characteristics of each lead by model number.

a. Electrodes

The cathode tip electrode transfers the electrical charge from the pulse generator to the desired cardiac surface (endocardium, epicardium, or myocardium) via the pacing lead. This electrical charge stimulates the myocardium, causing cardiac depolarization. The electrodes are either made of iridium-oxide coated titanium (IROX™) (models 431-07, 433-03, 435-07, 435-08, 437-07), carbon-coated (Biolite¹) titanium (431-04, 433-02, 435-02, 437-02) or a platinum-iridium alloy (models 435-05, 439-04, 439-07).

¹ Biolite is a trademark of Carbomedics, Inc., Austin, TX.

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TABLE 3. Characteristics of Intermedics Pacing Leads by Model Number.

Model No.	Chamber ¹	Polarity	Length ² (cm)	Electrode Material	Lead Body Material	Fixation	Connector
431-04	Ventricular	Unipolar	60	Biopore	Polyurethane	Passive/Tine	VS. 1
431-07	Ventricular	Unipolar	58	IROX	Polyurethane	Passive/Tine	VS. 1
433-02	Atrial	Unipolar	52	Biopore	Polyurethane	Passive/Tine	VS. 1
433-03	Atrial	Unipolar	52	IROX	Polyurethane	Passive/Tine	VS. 1
435-02	A/V	Unipolar	60	Biopore	Polyurethane	Active/Screw	VS. 1
435-05	A/V	Unipolar	60	Pt/Ir	Polyurethane	Active/Screw	VS. 1
435-07	A/V	Unipolar	58	IROX	Polyurethane	Active/Screw	VS. 1
435-08	A/V	Unipolar	58	IROX	Polyurethane	Active/Screw	VS. 1
437-02	Ventricular	Unipolar	60	Biopore	Silicone	Passive/Tine	VS. 1
437-07	Ventricular	Unipolar	60	IROX	Silicone	Passive/Tine	VS. 1
439-04	A/V ³	Unipolar	45	Pt/Ir	Polyurethane	Active/Suture	VS. 1
439-07	Ventricular ⁴	Unipolar	35	Pt/Ir	Silicone	Active/Screw	VS. 1

¹A/V - Atrial and Ventricular

²Nominal Lengths. Other lengths available upon request.

³Epicardial lead

⁴Myocardial Lead

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b. Lead Body

The conductor coils, constructed of three nickel-cobalt alloy wires wound uniaxially (trifilar), transmit electrical activity to and from the heart. Electrical isolation between the connectors and the body environment is provided by an sheath surrounding the conductor coil; which also contributes to the structural strength of the leads. The sheath may be made of polyurethane (models 431-04, 431-07, 433-02, 433-03, 435-02, 435-05, 435-07, 435-08, 439-04) or silicone rubber (models 437-02, 437-07, 439-07).

c. Tip Fixation

The passive fixation mechanism of the lead tip of the models 431-04, 431-07, 433-02, 433-03, 437-02, and 437-07 lodges among the trabeculae in order to prevent dislodgement or movement of the tip electrode from the endocardium. The tip fixation mechanism, made of silicone rubber, is a trailing tines design with radial projections 45° to the axis of the lead body.

The active fixation mechanism of the lead tips of the models 435-02, 435-05, 435-07, and 435-08 consists of a nickel-cobalt helical corkscrew which is fixed in the endocardium in order to prevent dislodgement or movement of the tip. The model 435-05 and 435-07 pacing leads both have a unique feature which provides a protective soluble Polyethylene Glycol (PEG) capsule over the fixation mechanism while the lead is passed through the venous system. Within 2 to 4 minutes, the PEG dissolves allowing fixation of the lead into the cardiac tissue. The model 435-08 features an extendable/retractable helical corkscrew. The corkscrew remains retracted until extended by the physician for placement into the endocardium.

The active fixation mechanism of the model 439-07 lead tip consists of a platinum-iridium helical corkscrew which is fixed in the myocardium over the ventricle. The active tip fixation mechanism of the model 439-04 is constructed of silicone rubber and sutured to the epicardium on either the atrium or ventricle.

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d. Connector Assembly

For all Intermedics pacing lead models, the connector pin (cathode) made of 316 stainless steel, provides the electrical and mechanical connection between the pulse generator and pacing lead. The connector sleeve and seals are made of silicone rubber and provide an insulating seal between the lead and the header of the pulse generator. The connector dimensions are designed to meet the requirements of the VS. 1 standard.

3. **Performance**

The Intermedics pacing leads and accessories are intended for use with implantable pulse generators. Based upon the results of qualification testing, the performance of the leads manufactured with the CFC-free manufacturing process is expected to be equivalent to the performance of the commercially available leads and accessories manufactured using Freon-TMS.

D. **ALTERNATIVES**

The alternatives to the use of pacing leads and accessories are similar to those described for pulse generators. Surgery or drug therapy have been stated as alternatives to cardiac pacing in certain instances. However, when a cardiac pacing system is employed, the side effects of drugs and/or the risks of surgery make these alternatives less desirable.

Other commercially available pacing leads and accessories provide another alternative to the use of Intermedics pacing leads manufactured using the CFC-free process.

E. **POTENTIAL ADVERSE EFFECTS**

The potential adverse effects associated with the use of pacing leads and accessories may include intermittent or continuous loss of pacing or sensing produced by factors such as displacement of the electrode, unsatisfactory

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electrode position, breakage of the conductor or its insulation, an increase in thresholds, or poor electrical connection to the pulse generator. As with the introduction of any foreign object into the body, infection can result from the use of pacing leads and accessories. These complications can occur during implantation, explantation, or at any time postoperatively and may require noninvasive or invasive management techniques.

When subclavian venipuncture is used for endocardial lead introduction, "extremely medial" insertion of a lead and/or "anatomic abnormalities" may contribute to conductor fracture². Perforation of the ventricular wall may cause phrenic nerve stimulation or diaphragmatic muscle stimulation. Cardiac tamponade has been reported from instances of lead perforation.

When removing an implanted endocardial lead, if the connector is cut off, the lead's insulation tubing, under sufficient traction, may separate from the lead conductor and slide off, leaving an exposed conductor coil in the heart and vein.

When using an epicardial or myocardial lead, conditions may occur that are associated with risks inherent in open chest surgery, such as pulmonary difficulties and, rarely, cardiac tamponade.

²Stokes K, et al: A possible "new" complication of subclavian stick: Conductor fracture, PACE, 10:748, 1987 (Abstract).

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F. SUMMARY OF STUDIES

1. Biocompatibility Studies

All of the tissue/fluid contacting materials of the pacing leads and accessories have been evaluated for biocompatibility in both *in vitro* and *in vivo* test systems and subjected to the following tests:

- Hemolysis Test
- MEM Elution Cytology
- Ames Mutagenicity
- USP Class V
- Intramuscular Implantation Test
- Maximization Sensitization Test
- USP Pyrogen Test

Based upon the test data, the materials above were not found to present any toxic liability under physiological conditions. Therefore, the tissue/fluid contacting materials of this pacing system are considered biocompatible.

In order to ensure continued biocompatibility of these materials when manufactured utilizing the IPA/heptane blend, the hemolysis and cytotoxicity tests were repeated for the following materials:

- Silicone tubing cleaned with IPA/heptane,
- 80A polyurethane tubing cleaned with IPA/heptane,
- 55D polyurethane tubing cleaned with IPA/heptane.

Based upon the results of these tests, the materials continue to be biocompatible when processed with the IPA/heptane blend.

2. Qualification Testing

Qualification testing was performed on the models 431-07 and 435-08. These lead models were selected as they consist of processes representative of the changes in the manufacturing processes of leads and

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accessories as a result of the elimination of Freon-TMS. These processes include:

- Cleaning (degreasing) of silicone, polyurethane, and metal parts
- Swelling of silicone tubing and parts
- Softening and lubricating of polyurethane tubing
- Mechanical assembly of components

G. CLINICAL SUMMARY

The clinical experience of the commercially available Intermedics pacing leads and accessories has resulted in an extremely low incidence of clinical complications, demonstrating its effective performance in human implantation. Because of the favorable biocompatibility and qualification test results, it is expected that the pacing leads and accessories manufactured with the CFC-free process will perform with comparable efficacy.

H. MANUFACTURING/STERILIZATION

Intermedics utilizes environmental controls in the manufacturing facilities which are designed, maintained and closely monitored to achieve an efficacious environment for manufacturing all products. The manufacturing environment is routinely monitored for particle counts, humidity, temperature, and static electricity controls. Additionally, bioburden testing is performed on all products.

Vendors of purchased material must be "approved" based upon a quality survey in which Intermedics' field engineers determine whether the vendor has the capability of consistently supplying material that will meet Intermedics' standards. Each quantity of purchased material is assigned a lot number and acceptance or rejection is determined based upon an inspection (conducted on a statistical sampling basis) performed to Intermedics' Engineering specifications.

The finished pacing lead and accessories are packaged in the formed pockets of an inner blister tray which is closed by heat sealing a peelable cover around the periphery. This inner blister is then placed into an outer blister which is closed

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by heat sealing a second peelable cover to it. Cover material is microbial penetration resistant, water resistant, and puncture resistant as suitable for this application.

Intermedics sterilization procedures for pacing leads and accessories utilize ethylene oxide (EO) sterilizers set for specific parameters derived using methods described in the 1988 AAMI guideline, Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices.

Upon release from sterilization, pacing lead and accessories are packaged into a carton and the boxed product is inspected prior to being routed to the Finished Goods Inventory area.

I. CONCLUSION

The information presented in this submission for the Intermedics Models 431-04, 431-07, 433-02, 433-03, 435-02, 435-05, 435-07, 435-08, 437-02, and 437-07 endocardial pacing leads, model 439-04 epicardial pacing lead, model 439-07 myocardial pacing lead, implantable accessory models 365-07, 365-09, 365-14, 365-17, 365-19, 365-22, 365-33, 365-34, 365-44, 365-49, 366-13, 366-15, 366-27, 366-28, 366-29, and 366-30, and non-implantable accessory models 365-62, 365-77, 365-29, 366-02, 366-17, and 367-01, demonstrates that the intended use of these devices does not differ from that of the commercially available predicate models.

The clinical experience of the Intermedics endocardial pacing leads and accessories has resulted in an extremely low incidence of clinical complications, demonstrating their effective performance in human implantation. Because of the similarity in design and materials, the pacing leads and accessories can be expected to perform with comparable efficacy.

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